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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/857,739	06/08/2001	John Russell Robertson	02332-0020 49409-264826	9829
23370	7590	11/01/2005	EXAMINER	
JOHN S. PRATT, ESQ KILPATRICK STOCKTON, LLP 1100 PEACHTREE STREET ATLANTA, GA 30309			YU, MISOOK	
			ART UNIT	PAPER NUMBER
			1642	

DATE MAILED: 11/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/857,739

Applicant(s)

ROBERTSON ET AL.

Examiner

MISOOK YU, Ph.D.

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-4 and 52-66 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3,4,52-54 and 61-66 is/are rejected.
- 7) ☒ Claim(s) 2 and 55-60 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>5/9/05, 8/12/05</u> | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Claims 1-4, 52-66 are pending and under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

This Office action contains new grounds of rejection.

#### ***Priority***

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in United Kingdom on 10 December 1998. It is noted, however, that applicant has not filed a certified copy of the GB9827228.9 application as required by 35 U.S.C. 119(b). This application is a 371 and the Office will try to obtain the GB9827228.9 application through the international bureau responsible for supplying the document.

#### ***Claim Rejections - 35 USC § 112, Withdrawn***

The rejection of claims 59, and 60 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is withdrawn in view of the amendment.

All rejections of record under **35 U.S.C. 102(b)**, and also under **35 U.S.C. 103(a)** are **withdrawn** in order to compare the claimed invention with the full journal article, i.e. Rao et al., (1988, IDS #1 filed on 05/19/2005, Am J obstet Gynecol, July 1998, vol. 159, pages 94-98) instead of the corresponding abstract by Rao et al, which was cited in the previous Office action.

***The Following Are New Grounds of Rejection***

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites, "which are derived form the same species as the mammal from which the sample has been obtained". It is not clear whether the limitation modifies the immediately preceding phrase, which is "the cancer-associated protein marker" or the antibody the immediately preceding noun, "the cancer-associated protein marker" binds to, i.e. "mammalian autoantibodies". The claimed method requires (1) a sample, which contains a modified form of a wild-type protein; (2) a reagent, which is an autoantibody to detect the modified form of a wild-type protein in a serum sample. Therefore, it appears that the phrase starting with "which" modifies the autoantibodies, not the antigen. Deleting the immediately preceding phrase, which is "the cancer-associated protein marker" would obviate this rejection.

***Claim Rejections - 35 USC § 102***

Claims 1, 3, 4, 52, 53, 54, 62-66 under 35 U.S.C. 102(b) as being anticipated by Rao et al., (1988, IDS #1 filed on 05/19/2005, Am J obstet Gynecol, July 1998, vol. 159, pages 94-98).

Claims 1, 3, 4, 52, 53, 54, 62-66 are drawn to method of detecting a modified form of a cancer-associated protein marker in a bodily fluid from a human having a cancer using polyclonal autoantibodies obtained from a human.

Applicant argues that Rao reference fails to disclose method of detecting a modified form of a wild-type protein, does not have a control to exclude cross-reactivity, and the reference is not enabled to make and use the autoantibodies. Applicant also argues that the Rao reference fails to identify antigen, and fails to describe antibodies used in the claimed invention because the antibody in Rao reference was from individual patients, and this antibody might not work for other patients.

These arguments have been fully considered but found unpersuasive. The claimed method as currently construed requires (1) a sample, which inherently has a modified form of a wild-type protein; (2) a reagent, which is an autoantibody to detect the modified form of a wild-type protein inherently present in a serum sample. The claims as currently construed does not have any manipulative step in order to detect only the modified form of a wild-type protein. The instantly claimed invention also allows the cross-reactivity if the active reagent of autoantibodies happen to cross-react with something other than a modified form of a wild-type protein. The instantly claimed invention does not require the identity of the antigen, nor requires highly sensitive autoantibodies. Applicant's argument is considered not commensurate in scope of the claims. In other words, the claimed invention requires autoantibodies as defined at the specification at page 3, lines 29-33, and a sample from body fluid of mammal, and detection of complex between the autoantibody and a protein in a body fluid.

Rao et al., teach autoantibodies that meet the definition of the instant specification at page 3, lines 29-33, and also method of detecting complex formed between the autoantibody and an antigen present in a sample from body fluid of human ovarian cancer patients. Note Table II at page 93, and ELISA assay. As for claim 66, the active steps of the instant claim and those of the art are the same. The intended use of the instantly claimed invention i.e. for therapy consideration is not given patentable weight. The claimed invention is drawn to detect a cancer-associated antigen using the instantly claimed active steps. Thus, Rao et al., anticipate claims 1, 3, 4, 52, 53, 54, 62, and 66.

### ***Conclusion***

The claims indicated as being objected in the Summary is because they depends on the rejected base claim.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 571-272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "misook yu", with a stylized flourish at the end.

MISOOK YU, Ph.D.  
Examiner  
Art Unit 1642